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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,576	10/17/2005	Mitsuharu Hirai	TOYA114.008APC	4658

20995 7590 04/29/2008
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EXAMINER

STAPLES, MARK

ART UNIT	PAPER NUMBER
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1637

NOTIFICATION DATE	DELIVERY MODE
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04/29/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/553,576	Applicant(s) HIRAI, MITSU HARU	
	Examiner Mark Staples	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01/23/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment of claim 18 and the cancellation of claims 1-17 and 22-24 in the paper filed on 01/23/2008 is acknowledged.

Claims 18-21 are pending and at issue.

Applicant's arguments filed on 01/23/2008 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections and Rejections that are Withdrawn

2. The objection to the abstract is withdrawn in light of Applicant's amendment of the abstract.

Sequence Compliance

3. It is acknowledged that Applicant has amended the description of the Figures 4 and 5 to bring the sequences of those figures in compliance with Sequence Rules.

Claim Objection Withdrawn

4. The objection to claim 18 is withdrawn in light of Applicant's amendment to recite the elected probe sequences.

Rejections that are Maintained

Claim Rejection Maintained - 35 USC § 103

5. The rejection of claims 18-21 under 35 U.S.C. 103(a) as being unpatentable over Critchley (WO 02/072875 published 19.09.2002) and Buck et al. (1999); as evidenced by Froguel et al. (1993) and by Howell et al. (1999) is maintained.

Applicant's arguments filed 01/23/2008 have been fully considered but they are not persuasive.

Critchley

Applicant argues that Critchley does not teach the probes of SEQ ID NO 21 and 22 and does not teach where the 3' end of the probe is cytosine which is labeled with the fluorescent dye.

In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a probe with an end cytosine labeled with a fluorescent dye) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988

F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is noted that claim 18 does not recite where the probe is labeled with the fluorescent dye.

In response to applicant's argument that Critchley does not teach a probe ending with a cytosine, this is not so. Critchley teaches probes ending in cytosine, see for example the sequences for SEQ ID NOs: 15, 18, 19, and 23.

Buck et al.

Applicant argues that Buck et al. do not teach the probes of the claimed invention, as Buck et al. teach that a multitude of shorter sequences within a larger sequence are usable as probes; whereas only certain probes (of many possible) function in the claimed method. However, Buck et al. is not relied upon for the selection of optimized probes from the possible probes, Critchley and Howell et al. are relied upon for this teaching as given below.

Applicant's Arguments Not Supported by the Specification

Applicant asserts that page 29, Table 9, and Figures 4-6 of the instant Specification provide support for the arguments that the following would not have been recognized by one of ordinary skill in the art: (1) the probe ending in cytosine is an important element first discovered by Applicant; and (2) the binding of the sequences of SEQ ID NOs: 21 and 22 to nucleotide position 230 of SEQ ID NO: 2 is an important element first discovered by Applicant. However, Examiner does not find support in the specification for these being elements first discovered by Applicant.

First, in regards to the end cytosine the specification merely states: "Then, the probes having C at the ends shown in Table 9 were designed" (see last paragraph on p. 27). No criteria is given for how these probes "were designed". It is not even clear that "having C at the ends" is the aspect of the probes which "were designed". Thus and as disclosed in the instant specification, the probes of Critchley meet the same threshold of design of the instant probes; as Critchley has designed probes ending in cytosine (see for example the sequences for SEQ ID NOs: 15, 18, 19, and 23).

Second, in regards to nucleotide position 230 being important in probe design, there is no support in the specification for one of ordinary skill in the art to realize this. The specification on p. 29 does not disclose that position 230 is important but merely conveys that "so long as the polymorphism site is included" (the site here being position 243) the probe can be used (see the last sentence of the first paragraph on p. 29). As to optimizing which probe sequences might be better for detecting a mutation, both Critchley (entire publication, especially the last paragraph on p. 14) and Howell et al. (see 3rd paragraph on p. 88) teach this.

Thus the claimed invention was obvious in view of the teachings of Critchley, Buck et al., and Howell et al.; and the rejection is maintained.

Conclusion

6. Claims 18-21 are not free of the prior art.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples

/M. S./

Examiner, Art Unit 1637

April 23, 2008

/Kenneth R Horlick/

Primary Examiner, Art Unit 1637